VERMONT
DEPARTMENT OF HEALTH

VACCINE MANAGEMENT PROTOCOL

PROCEDURES FOR VACCINE STORAGE AND HANDLING

STANDARD OPERATING PROCEDURES

- A person should be designated "in charge" of vaccines and work with the Vermont Department of Health to gain knowledge and understanding of vaccine storage and handling policies. A back-up person should also be designated.
- Temperatures should be recorded **twice** on a daily basis at the beginning and end of the clinic day.
- Temperature logs **must** be kept for three years.
- Refrigerators **need** to be kept above freezing. Temperatures **must** maintain a temperature of 2 - 8 degrees C or 35 - 46 degrees F. Vials/syringes of vaccine do not have to be frozen solid to be considered frozen and unable to be effective. **STRIVE FOR 5 DEGREES C OR 40 DEGREES F!**
- Freezer temperature should be at – 15 C (5 F) or colder.
- When out of range temperatures are found, corrective action **must** be taken. DOCUMENT all action taken on the back of the temperature logs provided by the Vermont Department of Health Immunization Program.
- **Do not** make assumptions about vaccine viability when found outside of the recommended temperature range. Call the Immunization Program for further assistance.
- Vaccines should be labeled clearly to differentiate what is state-supplied and privately purchased by the provider office.
- Conduct monthly inventory to assure rotation of vaccines. Short dated vaccine **must** be used first.
- When the vaccine is nearing 30 – 60 days prior to expiration and you will not be able to use it, return the vaccine to the Vermont Department of Health District Health Office so it can be redistributed elsewhere. If vaccine does expire, it **must** be returned to the Vermont Department of Health District Health Office.
- Design a plan for mechanical or power failure that will assure vaccine viability - a template is attached.

VACCINE MANAGER CONTACT INFORMATION

The person in charge of vaccine storage and handling and the back-up person are:

Name: _____ **Home Telephone Number:** _____

Back-up Name: _____ **Home Telephone Number:** _____

EQUIPMENT

THERMOMETERS:

- All refrigerators and freezers that house vaccine **must** have their own certified and calibrated thermometer.
- Thermometers **must** be placed in the middle of the unit-not touching the floor, walls or the sides of the unit.
- Call the Vermont Department of Health Immunization Program if you need a new or replacement thermometer(s).

REFRIGERATOR(S):

- A standard household style refrigerator is sufficient for storing vaccines.
- Vaccines should be stored in the center of the refrigerator.
- **THERE SHOULD BE NO VACCINE IN THE DOOR OR CRISPER BINS OF THE REFRIGERATOR!** Vaccine stored in the refrigerator door experiences temperature changes each time the door is opened.
- Open-weave, plastic storage baskets are fine for containing vaccines.
- MMR should be stored in the box that it came in because the vaccine is light sensitive.
- Diluent for Merck vaccines (MMR) can be stored in the refrigerator or at room temperature. Saline Hib diluent **must** be stored with the Hib vaccine in the refrigerator because the diluent and vaccine lot number must stay together.
- Food should **never** be stored in the refrigerator with vaccine.
- Place plastic bottles of water in the door. Remove the crisper bins in the refrigerator and replace with water bottles. Water bottles help maintain internal refrigerator temperatures.
- **"Do Not Disconnect"** signs/stickers should be posted on the refrigerator and on the circuit breaker. These signs/stickers are available from the Vermont Department of Health Immunization Program.

FREEZER(S):

- Freezer temperatures **must** maintain 5 degrees F or colder or -15 C or colder.
- Ice packs in the freezer unit help maintain freezer temperature as the unit defrosts. Varicella and LAIV vaccine **must** be off the freezer floor and surrounded with ice packs. The defrosting cycle can be as frequent as every 6 hours and as infrequent as every 24 hours. The freezer operates by heating the floor by several degrees to take the frost off the sides of the unit.
- Varicella vaccine should be stored in the box that it came in because the vaccine is light sensitive.
- Diluent for Merck vaccine (Varicella vaccine) can be stored at room temperature or in the refrigerator. It cannot be frozen.
- An indicator for freezer temperatures being unstable is to place a paper cup in the freezer with water and let it freeze. Once it is frozen, place a penny on top of the frozen water and check each day to see if the coin is moveable on the ice. If the coin is stuck on the ice, thawing has occurred since you last checked.

PLANNING FOR AN EMERGENCY

BACK-UP SYSTEM:

If you do not have a back-up generator, identify a location that has one (i.e. local hospital, retirement home, fire station or Red Cross.) Make an arrangement with the site to store your vaccine when your vaccine storage equipment cannot be fixed or the power cannot be restored within six hours.

Back-up Location: _____

Telephone Number: _____

Before moving your vaccine, call the location to ensure that their power is functional.

STAFF TRAINING/POSTED INFORMATION:

Post your vaccine emergency/recovery plan on or near the vaccine storage equipment.

If the building has lost electrical power, check with building maintenance to ensure that a time for the restoration of electrical power can be determined. If this cannot be determined, or is longer than six hours, implement the following procedures outlined in the **"Action Plan For Vaccine Storage Emergency"**.

ACTION PLAN FOR VACCINE STORAGE EMERGENCY

SUPPLIES TO HAVE ON HAND:

- Cooler(s)
- Frozen ice packs and cold packs
- Calibrated thermometer
- Insulation - such as Styrofoam peanuts or bubble wrap. The purpose of the insulator is to separate vaccine from direct contact with ice packs.
- Large zip lock bags - it is recommended to double bag vaccine to reduce any risk of contamination.

DURING A SHORT-TERM POWER SHORTAGE (less than approximately 6 hours):

VACCINE(S) IN THE REFRIGERATOR:

Do not open the refrigerator door until the power shortage is resolved. Record the refrigerator temperature at time of failure and continue to monitor the temperature until it reaches 2 - 8 degrees C or 35 – 46 F once the power has been restored. Record the duration of increased temperature exposure and provide data on the maximum temperature and maximum duration of exposures to elevated temperatures. See URL: http://www.cdc.gov/nip/news/poweroutage_orig.htm

VACCINE(S) IN THE FREEZER:

Varicella and LAIV vaccines are extremely temperature sensitive; therefore, contact Vermont Department of Health Immunization Program at 1-800-464-4343 ext 7638 immediately for further action.

DURING A LONG-TERM POWER SHORTAGE (more than 6 hours):

VACCINE(S) IN THE REFERIGERATOR:

- ❖ Place ice packs on the bottom of the cooler and cover it with insulation.
- ❖ Place the vaccine on top of the insulation.
- ❖ If the weather is warm, place insulation on top of the vaccine with 1 – 2 more ice packs on top.
- ❖ If there is additional space in the cooler, use fillers.
- ❖ Tape the lid on the cooler.
- ❖ Label the outside of the cooler "**VACCINE - REFRIGERATE IMMEDIATELY"**.
- ❖ Transport the vaccine in the passenger compartment of the vehicle and never in the trunk.

VACCINE(S) IN THE FREEZER:

- ❖ Varicella and LAIV vaccines are extremely temperature sensitive and can be **only** transported on dry ice. Contact the Vermont Department of Health Immunization Program immediately for further action.

AFTER A POWER SHORTAGE:

- Store the vaccines at appropriate temperatures. Make sure that the refrigerator/freezer is working properly. Do not discard affected vaccine.
- Mark the vaccine **"DO NOT USE"** and separate it from viable vaccine.
- Record the following information:
  a) Temperature of refrigerator: current _____ max _____ min _____
  b) Temperature of freezer: current _____ max _____ min _____
  c) Air temperature of room where refrigerator is located: _____
  d) Estimated amount of time the unit's temperature was outside of normal range: _____
  e) Prior to this event, was the vaccine exposed to temperatures outside of the recommended range? Yes or No
  f) Were water bottles in the refrigerator and ice packs in the freezer at the time of this event? Yes or No
  g) Use table on page 5 to fill in the vaccines affected by the event:

LIST OF AFFECTED REFRIGERATED VACCINES

Vaccine, Manufacturer and lot #	Expiration Date	# of doses	# of affected vials	Action Taken

AFFECTED VACCINE STORED IN THE FREEZER

Vaccine, Manufacturer and lot #	Expiration Date	# of doses	# of affected vials	Action Taken

For further information and help with getting information on vaccine viability, contact the Vermont Department of Health Immunization Program at 1-800-464-4343 ext. 7638. **DO NOT assume that vaccine cannot be salvaged**.

Manufacturers Phone numbers:

sanofi pasteur:	(800) 822-2463
Chiron Vaccines USA:	(800) 200-4278
GlaxoSmithKline:	(866) 475-8222
Merck & Co, Inc:	(800) 672-6372
Wyeth Vaccines:	(800) 999-9384
Med Immune, Inc:	(877) 358-6478

VACCINE STORAGE AND HANDLING CHART

VACCINE	CONDITION ON ARRIVAL	STORAGE REQUIREMENTS	RECONSTITUTION	NOTES
DTaP	Not frozen	DO NOT FREEZE Refrigerate at 2 - 8 C/35 – 46 F	Shake vial well	Rotate stock
HEPATITIS A AND B	Not frozen	DO NOT FREEZE Refrigerate at 2 - 8 C/35 – 46 F	Shake vial well	Rotate stock
HIB	Not frozen	DO NOT FREEZE Refrigerate at 2 - 8 C/35 – 46 F	Reconstitute with diluent provided	Rotate stock
INFLUENZA (inactivated)	Not frozen	DO NOT FREEZE Refrigerate at 2 - 8 C/35 – 46 F	Shake vial well Discard if drawn up > 8 hours	Rotate stock
IPV	Not frozen	DO NOT FREEZE Refrigerate at 2 - 8 C/35 – 46 F	Vaccine should look clear	Rotate stock
MMR	Frozen or refrigerated	PROTECT FROM LIGHT Refrigerate at 2 - 8 C/35 – 46 F – May be frozen	Discard if not used within 8 hours of reconstitution PROTECT FROM LIGHT	Rotate stock
PNEUMOCOCCAL	Not frozen	DO NOT FREEZE Refrigerate at 2 - 8 C/35 – 46 F	Shake vial well	Rotate stock
DT Td	Not frozen	DO NOT FREEZE Refrigerate at 2 - 8 C/35 – 46 F	Shake vial well	Rotate stock
Varivax/MMRV	Ship on dry ice only	MUST STAY FROZEN AT – 15 C OR COLDER PROTECT FROM LIGHT	Use within 30 minutes of reconstitution or discard PROTECT FROM LIGHT	MUST STAY FROZEN
LAIV (live attenuated influenza vaccine)	Must be frozen	MUST STAY FROZEN AT – 15 C OR COLDER	Use immediately after warming OR thaw in refrigerator for no more than 60 hours	MUST STAY FROZEN

MENINGITIS	Not frozen	DO NOT FREEZE Refrigerate at 2 - 8 C/35 – 46 F PROTECT FROM LIGHT (Menactra)	Shake vial well	Rotate stock
Tdap	Not frozen	DO NOT FREEZE	Shake vial well	Rotate stock
Rotavirus vaccine	Not frozen	DO NOT FREEZE Refrigerate at 2 - 8 C/35 – 46 F PROTECT FROM LIGHT	Administer orally	Rotate stock

Notes on the thermometer:

- The VDH supplied thermometer will need to have it's MIN and MAX cleared once it is has been installed and reaches temperature ranges in the acceptable range. To do this, hit "MODE" and "MEMORY CLEAR" and then "MODE" again. You can now check MIN and MAX temperatures reached in the unit by hitting "MODE".
- Use one certified, calibrated thermometer to record temperatures. Record temperatures at the beginning and at the end of the clinic day.
- The thermometer checks the temperature of the fluid in the bottle, mimicking what is happening in the vaccine bottles.
- The alarm is a tool, but it cannot take the place of checking temperatures. If you chose to activate the alarm, put the alarm switch in the ON position. Whenever the current temperature rises above the HI setting or falls below the LO setting the alarm beeps (not very loudly) for one minute and then a three second beep sounds every minute thereafter for up to 12 hours.
- When the alarm rings……..evaluate the situation.
- If the temperature is too warm…….. has the door been opened frequently? If YES, shut the door and watch without any adjustment. Recheck in an hour.
- If the temperature is too cold…….check the placement of the thermometer. If the thermometer is near the cold air vent, move it to the center of the unit. You may need to readjust the temperature control of the refrigerator very slightly to warmer. The key here is to go slowly and watch. Don't adjust to the extreme end of the thermostat. One person should be responsible for adjusting and monitoring the effect of the adjustment.
- The freezer might alarm if the freezer is in a defrost cycle. Check the unit again in one hour. If the twice a day temperatures are in range, but the alarm is a bother…….shut it off.

After the alarm sounds:

- Move alarm button to OFF. Reset when the temperature reaches acceptable range level.
- Hit "MODE" button to see what the minimum and maximum temperatures reached were. This information will help with the decision making about vaccine viability.
- Hit "MEMORY CLEAR" to erase the MIN and MAX temperatures reached.
- Erratic readings, a faint display or no display may all be indications of a low battery.
- Replace with a fresh AA alkaline battery and reset the unit.

Battery Change:

- The unit needs to be reset after the battery has been changed
- Use a pointed object such as a paperclip to push the reset button
- Push the MODE button to display "HI-LO" use
- Set the HI and LO temperatures to 2 and 8 degrees (Fridge) or – 15 degrees (Freezer) using the green buttons on the back of the unit.
- NOTE: Be aware that the negative temperature setting can make it appear as a range. If you HI and LO setting on your thermometer reads "2 -8", the high is set at -8, rather than 8.

05/06